

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2007/017133

International filing date (day/month/year)
31.07.2007

Priority date (day/month/year)
03.08.2006

International Patent Classification (IPC) or both national classification and IPC
INV. G06F19/00

Applicant
SMITHS MEDICAL MD, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2007/017133

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

Box No. II Priority

1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43bis.1 and 64.1) is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2007/017133

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 5, 17, 19, 20

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☒ no international search report has been established for the whole application or for said claims Nos. 5, 17, 19, 20

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2007/017133

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has, within the applicable time limit:
- ☐ paid additional fees
 - ☐ paid additional fees under protest and, where applicable, the protest fee
 - ☐ paid additional fees under protest but the applicable protest fee was not paid
 - ☒ not paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 1-4, 6-9, 10-16, 18

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>2-4, 6-9, 11-16, 18</u>
	No: Claims	<u>1, 10</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-4, 6-9, 10-16, 18</u>
Industrial applicability (IA)	Yes: Claims	<u>1-4, 6-9, 10-16, 18</u>
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item IV

Lack of unity of invention

The application appears to lack unity within the meaning of Rule 13.1 PCT, since it does not relate to one invention only or to a group of inventions so linked as to form a single general inventive concept.

The application contains the following two separate inventions:

The first invention, claims 1-4, 6-9, 10-16, 18, relates to the modification of a patient specific protocol for the programming of a medical infusion pump, by providing a user interface configured to allow user adjustments of the patient specific pump parameters.

The second invention, claims 1, 5, 17, 19-20, relates to executability of a patient specific protocol on a medical infusion pump, by formatting the patient specific protocol to correspond to the format understood by the medical infusion pump.

These two inventions try to solve two different, independent problems and the only common general concept linking them together is the subject-matter of claims 1 and 10. However, this common concept is not novel and not inventive, see the documents cited in the search report (and Item V below), thus the requirement for unity of invention referred to in Rule 13.1 PCT is not fulfilled.

Independent claims 1 and 10, and the dependent claims 2-4, 6-9, 11-16, 18, constituting the invention first mentioned in the claims, and representing the main invention of the application, have thus been searched.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

- 1 Reference is made to the following documents:
 - D1: WO 96/20745 A (ABBOTT LAB [US]) 11 July 1996 (1996-07-11)
 - D2: US 2003/163088 A1 (BLOMQUIST MICHAEL L [US]) 28 August 2003 (2003-08-28)
 - D3: US-A-5 935 099 (PETERSON THOMAS L [US] ET AL) 10 August 1999 (1999-08-10)
 - D4: GB-A-2 312 055 (BAXTER INT [US]) 15 October 1997 (1997-10-15)

D5: WO 2005/056083 A (SMITHS MEDICAL MD INC [US]; BLOMQUIST
MICHAEL L [US]) 23 June 2005 (2005-06-23)

D6: WO 2006/073400 A (ADVANCED MEDICAL OPTICS INC [US]; CLAUS
MICHAEL J [US]) 13 July 2006 (2006-07-13)

- 2 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1 and 10 is not new in the sense of Article 33(2) PCT over prior art document D1 (see D1 at the passages cited in the search report).

The features added by the dependent claims are either known from D1 or form part of the general knowledge of the person skilled in the art. They do not appear to comprise anything which would go beyond the prior art to an extent that it could be considered as involving an inventive step (Article 33(3) and Rules 64 and 65 PCT).

- 3 Notwithstanding what has been said above, the subject-matter of claims 1 and 10 is also not new over prior art document D2 (see D2 at paragraphs 28, 118-123, 125-129, 225, 228, and Figures 12 and 13).

The features added by the dependent claims are either known from D2 or form part of the general knowledge of the person skilled in the art. They do not appear to comprise anything which would go beyond the prior art to an extent that it could be considered as involving an inventive step.

This applies likewise in view of prior art document D3 (see D3 in particular at col.21 l.41-45), D4 (see D4 at claims 1-18, in particular claims 12-18, and page 9 l.15 - p.11 l.4) or also D5 (see D5 at Figures 1 and 3, the abstract, the summary and in particular p.4 l.19 - p.5 l.27)..

- 4 Concerning the subject-matter added by dependent claims 4 and 13, it is additionally noted that adjustable slider bars were very well-known at time of priority of the application, see e.g. document D6 (see D6 at the abstract, the summary, Figures 3 and 5, paragraphs 25,27,28), and that it therefore not provides an inventive step.

Final remarks

It is not at present apparent which part of the application could serve as a basis for a new claim which might meet the requirements of the PCT. In case the applicant regards some particular matter as fulfilling the requirements of the PCT, and/or when entering the European Phase, it is appropriate to file new claims which take account of the above comments. The applicant should in addition indicate the difference of the subject-matter of the new claims vis-à-vis the state of the art and the significance thereof, in particular in respect of the technical effect provided by said difference. He should furthermore give an indication of the objective technical problem to be solved in view of the prior art (based on the technical effect provided by the differences), i.e. the aim and task of modifying or adapting the prior art to provide the said technical effect. Some further information needs to be provided to demonstrate why such a modification would not be obvious to the person skilled in the art, taking into account of the prior art and the common general knowledge. This might be shown e.g. by indicating advantageous and unexpected effects of the next version of the claimed subject-matter.